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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/812,283	03/19/2001	Robert L. Fischer	023070086121	2808

20350 7590 07/31/2003

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EXAMINER

MEHTA, ASHWIN D

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 07/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/812,283

Applicant(s)

FISCHER ET AL.

Examiner

Ashwin Mehta

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 15 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-10,12,13,15 and 17-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-10,12,15 and 17-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 May 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Note: On 15 May 2003, Applicants submitted a supplemental response to the Office action mailed 15 July 2003. On page 1 of that response, Applicants indicated that the paper contains the responses and amendments filed in the paper submitted on 14 January 2003, as well as a new response to the drawings and obviousness-type double patenting rejection. As the remarks in the paper submitted on 14 January 2003 were repeated in the paper submitted 15 May 2003, this Office action will only refer to the response submitted on 15 May 2003.

2. The objection to the specification for containing an embedded hyperlink is withdrawn, in light of its removal.
3. The objection to the sequence listing is withdrawn, in light of the submission of the substitute sequence listing.
4. The rejection of claims 9-15, 17-21, and 24 under 35 U.S.C. 112, 2<sup>nd</sup> paragraph, is withdrawn, in light of the claim amendments.

***Drawings***

5. The corrected or substitute drawings were received on 20 May 2003. These drawings are acceptable.

***Claim Objections***

6. Claim 1 remains objected to for the reasons of record stated in the Office action mailed 15 July 2002 under item 5. In the paper received 20 May 2003, Applicants indicate that the claim was amended as suggested (page 6, 1<sup>st</sup> full paragraph). However, the amendments to the claim do not include the suggested change.

Claim 1, as amended, is also objected to for the following informality: in line 5, the article "a" is missing before --promoter--.

***Double Patenting***

7. Claims 1, 2, 5-10, 12, 13, 15, 17-24 remain and new claims 25-29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6, 9-17, and 20-22 of U.S. Patent No. 6,229,064, for the reasons of record stated in the Office action mailed 15 July 2002. In the response submitted 15 May 2003, Applicants indicate that they will provide a terminal disclaimer when the claims have been indicated as otherwise allowable and if the rejection still applies (response, page 6, 2<sup>nd</sup> full paragraph). Applicants' intent is acknowledged. The rejection is maintained.

***Claim Rejections - 35 USC § 112***

8. Claim 2 remains and claims 15-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons of record stated in the Office action mailed 15 July 2002 under item 7.

Regarding claim 2: Applicants, in the paper submitted 15 May 2003, indicate that the word "about" was deleted (page 6, 3<sup>rd</sup> full paragraph). However, the amendment only appears in the marked-up version of the claim amendments, and not in the clean version.

In claim 15: the recitation, "modulating endosperm development" in lines 1-2 renders the claim and those dependent thereon indefinite. The claim is dependent on claim 1, which indicates that expression of the polynucleotide inhibits gene expression when introduced into a plant. However, the preamble of claim 15 indicates that endosperm development is "modulated," which encompasses any type of change, and broadens than the limitation of claim 1.

9. Claims 1, 2, 5-7, 9, 10, 12, 13, 15, 18, 20-24 remain and claims 25-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office action mailed 15 July 2002 under item 8. Applicants traverse the rejection in the

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paper received 15 May 2003. Applicants' arguments have been fully considered but were not found persuasive.

Applicants argue that amended claim 1 recites that the polypeptide comprises a WD40 repeat, and that the specification indicates that WD40 repeats are motifs involved protein-protein interactions (response, page 7, 2<sup>nd</sup> paragraph). However, this repeat is also present on proteins that have functions that are different from SEQ ID NO: 4 and other FIE polypeptides. Ach et al. (Plant Cell, 1997, Vol. 9, pages 1595-1606), for example, teach proteins containing WD40 repeats that interact with retinoblastoma proteins. Ach et al. also assert that WD-40 repeats are present has been found in a number of eukaryotic regulatory proteins, including G-proteins and the Arabidopsis COP1, which is involved in light-regulated signal transduction (pages 1596-1597). The presence of a WD40 repeat therefore does not correlate a structure with the functional activity expressed by SEQ ID NO: 4.

Applicants continue, arguing that the claims provide at least two structural limitations, percent identity with a reference amino acid sequence and the presence of a well-known protein motif, and that the specification thus defines a physical and structural property of the invention, as explicitly required by the court in *University of California v. Eli Lilly & Co.* (response, paragraph bridging pages 7-8). However, Applicants do not describe any structure that differs from SEQ ID NO: 4 by as much as 40% and which has the functional activity of SEQ ID NO: 4. The added limitation that the polypeptide encoded by the claimed nucleic acid molecule contains a WD40 repeat, does not correlate the structure of the polypeptide to the functional activity of SEQ ID NO: 4, as WD40 repeats are present on structures that have different functional activities. The specification does not describe any other domains or amino acid sequences of

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SEQ ID NO: 4 that are essential to its functional activity. Applicants also argue that the claims only encompass polynucleotides with a particular function (response, page 8, 1<sup>st</sup> full paragraph). However, again, Applicants have not described any structure that differs from SEQ ID NO: 4 by as much as 40%, while still containing a WD40 repeat, that also retains the functional activity of SEQ ID NO: 4.

10. Claims 1, 2, 5-7, 10, 12, 13, 15, 18, 20-24 remain and claims 25-28 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, for the reasons of record stated in the Office action mailed 15 July 2002 under item 9. Applicants traverse the rejection in the paper received 15 May 2003. Applicants' arguments have been fully considered but were not found persuasive.

Applicants argue that those of skill could have readily prepared and used the polynucleotides within the full scope of the claims (response, page 8, last paragraph). The Examiner maintains that that specification does not provide sufficient guidance in the amino acid sequences of SEQ ID NO: 4 that may be changed without changing its functional activity. As discussed above, Ach et al. teach that the WD40 domain is present in a variety of proteins having diverse functions. This domain alone is not responsible for the functional activity of SEQ ID NO: 4. The specification does not teach provide any guidance in how the other amino acid sequences may be changed.

Applicants also argue that the amended claims encompass antisense constructs, and sense constructs for sense suppression (response, page 9, 1<sup>st</sup> paragraph). However, as written, claims 1

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and 15 broadly indicate that expression of the polynucleotide will inhibit any gene expression. It is suggested that the claims be amended to indicate that FIE gene expression is inhibited. Further, claim 15 broadly encompasses modulating endosperm development in any manner, whereas the specification indicates that suppression of FIE3 gene expression only enhances endosperm development in the absence of fertilization. It is suggested that claim 15 also be amended to indicate this.

### *Summary*

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. No claim is allowed.

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***Contact Information***

Any inquiry concerning this or earlier communications from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

July 30, 2003



Ashwin D. Mehta, Ph.D.  
Primary Examiner  
Art Unit 1638